K053296
1/2

DEC 16 2005

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92

The assigned 510(k) number is: _____

Contact Person: Donna A. Crawford
Director, Domestic Regulatory Submissions
Mentor Corporation
201 Mentor Drive
Santa Barbara, CA 93111

Telephone: 805-879-6304
FAX: 805-879-6015

Date Prepared: November 23, 2005

Device Name and Classification

Proprietary Name:	Mentor Aris™ Suprapubic Surgical Kit
Common Name:	Pubourethral Support Tape
Classification Name:	Surgical Mesh, polymeric
Class:	Class II
Product Code:	OTN
CFR #:	§878.3300

Device Description

The Mentor Aris Suprapubic Surgical Kit consists of two components: the Mentor Aris Sling and a set of Introducers. The Mentor Aris Sling is an implantable, suburethral, support tape made from knitted monofilament polypropylene fibers. Two sterile, disposable flat curved Introducers necessary for implantation of the sling are also included in the Surgical Kit. The Introducers consist of a stainless steel needle with a plastic handle.

Substantial Equivalence Claim

The Mentor Aris Suprapubic Surgical Kit is substantially equivalent in material, function, performance and design to the Mentor Aris Trans-Obturator Tape and Surgical Kit cleared under 510(k) K050148, and to American Medical Systems' SPARC Sling System cleared under 510(k)s K011251, K013355, K020663 and K021263.

K053296 2/2

Indications for Use

Mentor Aris Suprapubic Surgical Kit is indicated for the surgical treatment of all types of stress urinary incontinence (SUI), and for female urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

Summary of Testing

The Aris Sling was demonstrated to be biocompatible under 510(k) K050148. The following biocompatibility testing was performed on the Aris Introducers: cytotoxicity per ISO 10993-5, and intracutaeous reactivity per ISO 10993-10. The results of the tests demonstrate that the Introducers are non-toxic and non-irritants.

Performance testing of the Aris Sling was previously performed under 510(k) K050148. The following testing was performed on the Aris Introducers: sling pull-out force from the eyelet; torque and tensile performance of the handle/needle interface; needle flexure characterization, and needle stiffness characterization. The results demonstrate that the Aris Introducers meet the required performance characteristic specifications for the intended use of the instruments.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Donna A. Crawford
Director, Domestic Regulatory Submissions
Mentor Corporation
201 Mentor Drive
SANTA BARBARA CA 93111

SEP 28 2012

Re: K053296
Trade/Device Name: Mentor Aris Suprapubic Surgical Kit
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: OTN
Dated: November 23, 2005
Received: November 25, 2005

Dear Ms. Crawford:

This letter corrects our substantially equivalent letter of December 15, 2005.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K053296

Indications for Use

510(k) Number (if known): K053296

Device Name: Mentor Aris™ Suprapubic Surgical Kit

Indications For Use:

The Mentor Aris Suprapubic Surgical Kit is indicated for the surgical treatment of all types of stress urinary incontinence (SUI), and for female urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

Prescription Use __X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Marlene Brechner

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K053296